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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,313	07/15/2005	David J. Rys	1282-P02956US01	6431
110 7590 07/02/2008 DANN, DORIMAN, HERRELL & SKILLMAN 1601 MARKET STREET SUITE 2400 PHILADELPHIA, PA 19103-2307				
EXAMINER				
PURDY, KYLE A				
ART UNIT		PAPER NUMBER		
1611				
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07/02/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/524,313

**Applicant(s)**

RYS ET AL.

**Examiner**

Kyle Purdy

**Art Unit**

1611

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02/07/2005, 10/08/2007 and 05/05/2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 5-10 and 24-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 11-21 and 23 is/are rejected.
- 7) ☒ Claim(s) 22 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of Application***

1. The Examiner acknowledges receipt of the arguments and amendments filed on 05/05/2008 wherein claim 11 has been amended.

2. Claims 1-33 are pending, claims 5-10 and 24-33 are withdrawn from consideration and claims 1-4 and 11-23 are presented for examination on the merits. The following rejections are made.

3. **NOTE**: claim 33 is currently listed as pending, it is currently withdrawn however. See restriction requirement mailed on 08/06/2007 and Applicants response to restriction requirement received on 10/08/2007.

### ***Response to Applicants' Arguments***

4. Applicants arguments filed 05/05/2008 regarding the objection of claim 3 made by the Examiner under Double Patenting have been fully considered and they are found persuasive. This objection is withdrawn.

5. Applicants arguments and amendments filed 05/05/2008 regarding the objection of claims 11-23 made by the Examiner under 35 USC 112, first paragraph (enablement) have been fully considered and they are found persuasive. This objection is withdrawn.

6. Applicants arguments filed 05/05/2008 regarding the objection of claim 22 made by the Examiner under 35 USC 103(a) over Nitz et al. (WO 99/33508) in view of DeLuca et al. (Pharm. Dosage Forms, Vol. 1, Parenteral Medications, 173-175, 1992) have been fully considered and they are found persuasive. This rejection is withdrawn.

7. Applicants arguments filed 05/05/2008 regarding the objection of claims 1-4, 11-21 and 23 made by the Examiner under 35 USC 103(a) over Nitz et al. (WO 99/33508) in view of DeLuca et al. (Pharm. Dosage Forms, Vol. 1, Parenteral Medications, 173-175, 1992) have been fully considered and they are not found persuasive.

8. Applicants arguments filed 05/05/2008 regarding the rejection of claims 1-4 and 11-23 made by the examiner under 35 USC 103(a) is **MAINTAINED** for the reasons of record in the office action mailed on 11/05/2007.

9. In regards to the 103(a) rejection, Applicant asserts the following:

A) There is no disclosure in the cited prior art to suggest to an artisan of ordinary skill that meta vs. para-substitution on the phenyl ring of the methylene bisphenol compounds called for in claim 1 would bring about a reasonable expectation for success; and

10. With respect to assertion A, the Examiner respectfully disagrees. See MPEP 2144.09 (I). It states that a rejection based on close structural similarity is 'founded on the expectation that compounds similar in structure will have similar properties'. It goes on, 'an obvious rejection based on similarity in chemical structure and function entails the motivation of one skilled in the art to make a claimed compound, in the expectation that compounds similar in structure will have similar properties.' The instantly claimed compounds are sufficiently the same and are being used for the same purpose as those in the applied reference to Nitz et al.. Furthermore, the instant rejection is not based on i) homologization and ii) ring walking as Applicant suggests. Homologization is not a basis for rejection here. Rather the rejection relies solely upon the obviousness of ring walking. Ring walking is common practice in the field of organic synthesis in hopes of identifying a structure with the greatest therapeutic properties. See Cammarata (J.

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Medicinal Chemistry, 1972, 15(6), 573-577). Cammarata is applied to show that ring walking is commonly done for identifying compounds with the greatest structure-activity relationship. To show how the structure-activity relationship is connected, Cammarata ring walks various halogens along an aromatic ring and measures their corresponding activity. Thus, moving substituents along a ring is common practice in the field of organic synthesis, especially in pharmaceutical synthesis.

**New Grounds of Objection**  
***Claim Objections***

11. Claim 22 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

**Maintained Rejections**  
***Claim Rejections - 35 USC § 103***

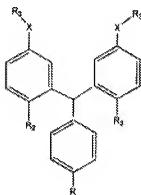
12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 1-4, 11-21 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nitz et al. (WO 99/33508) in view of DeLuca et al. (Pharma. Dosage Forms Vol. 1: Parenteral Medications, 1992, 173-175).

14. The claims of the instant application are drawn to a compound having the following structure wherein the species occupying the R1 position is propyl. The compound is used in a pharmaceutical composition, in an amount effective to attenuate infectivity of pneumovirus. The composition further comprises at least one supplemental active agent such as interferons, immunoglobins, antibiotics, etc. The composition may comprise ethanol from at least 50% to at least 90% of the composition in addition to propylene glycol, and water. Preferably however, the composition comprises 85% ethanol, about 10% propylene glycol and less than 5% water.

15. The teaching of Nitz et al. ('508) is drawn to compounds, compositions and methods for treating or preventing pneumovirus infection and associated diseases. The compounds use to treat pneumovirus have the following structure



The species which may occupy the X, R, R<sub>2</sub> and R<sub>3</sub> are identical to those of the instant application in that X may be -C=N, R may be propyl, R<sub>2</sub> is hydroxyl, and R<sub>3</sub> is 5-methyl-1-tetrazolyl (see page 4, line 15 - page 5, line 5 and Example 10). The difference between '508 and the instant application, R and R<sub>3</sub> respectively, is the position of the substituent on the benzene ring. The substituent of '508 is in the para position whereas the instant applications substituent is in the meta position. Typically structural homologs, either isomers (i.e. cis vs.

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trans) or positional isomers (i.e. meta vs. para), often have similar pharmacological properties. With that stated chemists of ordinary skill would contemplate making slight variations of a known compound in order to obtain compounds with better and improved properties. The compounds of the prior art would motivate such routine organic synthesis and optimization, leading to the instantly claimed compounds which possess efficacy as inhibitors of pneumovirus replication. See *In re Deuel*, 51 F.3d 1552, 1558, 34 USPQ2d 1210, 1214. The teaching of '508 also stipulates for the inclusion of supplemental active agents such as interferons, antibiotics, and immunoglobins.

16. The reference teaches that the carrier solvent of the pharmaceutically active compound can consist of any "pharmaceutically acceptable carrier medium" meaning that the carrier includes any and all solvents. This would necessarily encompass and motivate the inclusion of ethanol, propylene glycol and water. Still, however, '508 specifically fails to include ethanol, propylene glycol, and water in the pharmaceutical preparation.

17. The teaching of DeLuca et al ('DeLuca) is drawn to parenteral formulations and useful carrier vehicles thereof. On page 175, Section B, it is noted that most parenteral products are aqueous solutions. However, inclusion of water may have to be limited if the active compound is susceptible to chemical degradation (i.e. hydrolysis, racemization, etc.). It is stated that for non-polar substances possessing limited solubility in water, it is necessary to use co-solvents such as ethanol and propylene glycol. Although DeLuca does not specifically teach adding the ingredients together in the amounts claimed. The amount of a specific ingredient in a composition is a result effective parameter that any person of ordinary skill in the art would desire to optimize. The instantly claimed percentages of said solvents, as described above, could

readily be attained by routine experimentation and optimization.

18. Thus, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to combine the teachings of '508 and DeLuca because in doing so one would create a pharmaceutically active formulation suitable for safe administration to a patient. The instantly claimed compound are obvious as they are structural isomers of reference '508 and one of ordinary skill in the art would be motivated to make such modifications with the expectation that the compounds and compositions thereof would possess identical pharmacological properties as those taught by the reference. Moreover, the use of water, ethanol, and/or propylene glycol as a carrier medium would be motivated by '508 statements that all pharmacologically acceptable carrier mediums can be used to carry the drugs. This motivates one to look to the prior art of drug formulations where is found that solvents such as water, ethanol and propylene glycol are commonly used as a carrier medium. Furthermore, the specifically claimed percentages of said carrier do not qualify as patentable subject matter, as these values could found via routine experimentation and optimization. Therefore, it would have been obvious to a person of ordinary skill in the art to combine the teachings of '508 with that of DeLuca with a reasonable expectation of success.

### ***Conclusion***

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kyle A. Purdy whose telephone number is 571-270-3504. The examiner can normally be reached from 9AM to 5PM.



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17. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

18. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*/Kyle Purdy/  
Examiner, Art Unit 1611  
February 26, 2008*

*/MP WOODWARD/  
Supervisory Patent Examiner, Art Unit 1615*